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December 16, 1999

Document Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: DOCKET NO. 97N-484S

Dear Sir/Madam:

I would like to add a small comment from a user's perspective on the proposed FDA regulation of bone allografts as medical devices.

I certainly respect the Administrations position that certain bone allografts are being used in operations in lieu of or as replacements for metallic constructs. This is certainly the issue in certain types of spinal surgery cases.

I would like the Administration to place consideration into the degree and intensity such regulation should be implemented. If testing and verification of efficacy is required to the same degree as for metallic implants there may be a withdrawal and removal from market usage of many bone allografts. This may place certain restrictions on the ability of spinal neurosurgeons and orthopedists to perform surgical care in the near future.

I trust that the Administration will place this point into consideration.

Sincerely,

Anthony J. Hall, M.D., C.M.
Miami Neurosurgical Associates, P.A.

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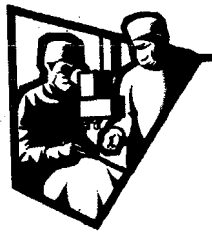

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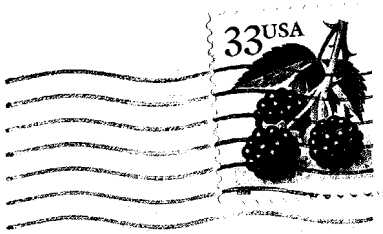

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